SCV2-SPX-EP Molecular Test Fact Sheet

Corteva Agriscience and Quantigen Biosciences with support from a grant from The Bill and Melinda Gates Foundation have developed an ultra-high throughput molecular test for SARS-CoV-2, the virus that causes COVID-19. The technology used in this PCR test has a vastly greater capacity and lower cost than existing COVID-19 molecular tests. The implementation of this technology will bring testing to more people than ever before, including underserved and vulnerable populations. Corteva plans to test approximately 100,000 samples from individuals across the United States in a single day to demonstrate the daily throughput of this testing platform. Your sample is being tested as part of this demonstration. This Fact Sheet provides information on the SCV2-SPX-EP Molecular Test.

What is SARS-CoV-2?

- SARS-CoV-2 is a virus that causes COVID-19. For the most up to date information on COVID-19 please visit the CDC Coronavirus Disease 2019 (COVID-19) webpage: https://www.cdc.gov/coronavirus/2019-ncov/index.html

What is the SCV2-SPX-EP Molecular Test?

- The test uses PCR for the qualitative detection of SARS-CoV-2 nucleic acid from a self-administered nasal swab.
- The analysis will be performed in the Pioneer Hi-Bred International, Inc. (Corteva Agriscience) laboratory, which is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, by qualified laboratory personnel.

What is different about this test?

- The SARS-CoV-2 Molecular Test uses a novel collection tube that enables automation and high-throughput molecular testing.
- Existing molecular tests are expensive; however, this inexpensive method can be adapted to be used worldwide to help underserved populations and expand community access to testing.

Is this test accurate?

- Yes. The sensitivity of this test is similar to many widely used PCR tests designed to measure SARS-CoV-2 nucleic acid. This test has a limit of detection of 250 copies per swab.

Who is eligible to participate?

- Participation is limited to asymptomatic individuals 18 years and older.

Is this a clinical study?

- No. The test has been validated under the U.S. Food and Drug Administration (FDA) analytical and clinical validity guidelines

What are some benefits and risks of the test?

- Benefits
  - The test is provided at no cost.
  - Sample collection is simple through a self-administered nasal swab.
- Risks
  - Potential discomfort during sample collection.
  - Possible inconclusive or incorrect test results.

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How will the results be reported?

- Results will be returned electronically to all participants within 24-48 hours. Test results will be specified as 'detected', 'not detected', or 'inconclusive'. All 'detected' results will also be reported to the applicable state department of health or other applicable government agency as required by law.

What does it mean to have a 'detected', 'not detected' or 'inconclusive' test result?

- A 'detected' test result is indicative of the presence of SARS-CoV-2 nucleic acid. However, it does not rule out bacterial infection or co-infection with other viruses. As with all laboratory tests, there is a chance that this test could give an incorrect 'detected' result (a false-positive result). The observed false-positive rate for this test is <1%.
- A 'not detected' test result indicates that the SARS-CoV-2 nucleic acid was not detected in the sample but does not preclude SARS-CoV-2 infection. As with all laboratory tests, there is a chance that this test could give an incorrect 'not detected' result (a false-negative result). The observed false-negative rate for this test is <5%.
- An 'Inconclusive' test result indicates that the test was unable to confirm the presence or absence of SARS-CoV-2 nucleic acid in the sample.
- Please contact your healthcare provider if you wish to discuss your test result.

Will my personal data and privacy be protected and secure?

- Yes.

How much does the test cost?

- The test is being provided at no cost to the participants.

Is the test FDA approved?

- Assay validation has been completed under the U.S. Food and Drug Administration (FDA) analytical and clinical validity guidelines as well as with consultation with the FDA. Notification regarding the validation of this laboratory-developed test LDT has been provided to the FDA.

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